

## UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

## NOTICE OF ALLOWANCE AND ISSUE FEE DUE

000826 HZ12/0621 ALSTON % BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE NC 28280-4000

APPLICATION NO.	FILING DATE	TOTAL C	CLAIMS	EXAMINER AN	DATE MAILED		
09/446,402	12/20/99	004	MCGARRY,	S		1635	06/21/01
rst Named ACK JR.,		35	USC 154(b)	term e	×¢. =	0 Days	п .

TITLE OF APPOSITIONS AND METHODS FOR ACTIVATING GENES OF INTEREST

ATTY'S DOCKET NO	CLASS-SUBCLASS	BATCH NO.	APPLN, TYPE	SMALL EN	TITY	FEE DUE	DATE DUE
1 5722-2	435-069.	100 [112]	UTIL.ITY	YES	\$ <b>6</b> 2	:0.,00	09/21/01

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED</u>.

## HOW TO RESPOND TO THIS NOTICE:

- Review the SMALL ENTITY status shown above.
   If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
  - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
  - B. If the status is the same, pay the FEE DUE shown above.

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- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.

  Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

patent and trademark office copy

	Application No.	Applicant(s)	Applicant(s)  BLACK JR., CHARLES ALLEN				
	09/446,402	BLACK IB CH					
Notice of Allowability	Examiner	Art Unit	ANLES ALLEN				
		1					
	Sean McGarry	1635					
The MAILING DATE of this communication appears All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance and Issue ITHIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATE initiative of the Office or upon petition by the applicant. See 37 C	(OR REMAINS) CLO Fee Due or other app NT RIGHTS. This ap	SED in this application. If not inc ropriate communication will be map plication is subject to withdrawal	luded ailed in due course.				
1. This communication is responsive to <u>4/9/01</u> .							
2. The allowed claim(s) is/are 2-4 and 16.							
<u> </u>	ings filed on are acceptable as formal drawings.						
Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some* c) ☐ None of the:							
<ol> <li>Certified copies of the priority documents have</li> </ol>	of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this national stage application from the							
International Bureau (PCT Rule 17.2(a)).							
* Certified copies not received:							
5. Acknowledgement is made of a claim for domestic priority	under 35 U.S.C. § 119	∂(e).					
Applicant has THREE MONTHS FROM THE "MAILING DATE" of below. Failure to timely comply will result in ABANDONMENT of FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTI complying with the REQUIREMENT FOR THE DEPOSIT OF BELOW.	this application. THI: TUTE OATH OR DEC OLOGICAL MATERI E OF INFORMAL API	S THREE-MONTH PERIOD IS NO CLARATION. This three-month AL is extendable under 37 CFR PLICATION (PTO-152) which give	OT EXTENDABLE period for R 1.136(a).				
the oath or declaration is deficient. A SUBSTITUTE OAT  7. Applicant MUST submit NEW FORMAL DRAWINGS	H OR DECLARATION	115 REQUIRED.					
(a) ☐ including changes required by the Notice of Draftsper	son's Patent Drawing	Review( PTO-948) attached					
1) hereto or 2) to Paper No							
(b) ☐ including changes required by the proposed drawing correction filed, which has been approved by the examiner.							
(c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No							
Identifying indicia such as the application number (see 3 should be filed as a separate paper with a transmittal lett			The drawings				
8.  Note the attached Examiner's comment regarding REQUIF	REMENT FOR THE D	EPOSIT OF BIOLOGICAL MATE	ERIAL.				
Any reply to this letter should include, in the upper right hand corr applicant has received a Notice of Allowance and Issue Fee Due, ALLOWANCE should also be included.	ner, the APPLICATION the ISSUE BATCH N	NUMBER (SERIES CODE / SE UMBER and DATE of the NOTIC	:RIAL NUMBER). If )E OF				
Attachment(s)							
1  Notice of References Cited (PTO-892) 3  Notice of Draftperson's Patent Drawing Review (PTO-948) 5  Information Disclosure Statements (PTO-1449), Paper No. 2 7  Examiner's Comment Regarding Requirement for Deposit of Biological Material	4☐ In ≤ 6⊠ E	otice of Informal Patent Application terview Summary (PTO-413), Patentiner's Amendment/Comment warminer's Statement of Reasons, ther	per No				

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## **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eric Kron and Murray Spruill on 6/19/01.

A communication was mailed to applicant on 6/19/01 that indicated that the response filed 4/9/01 was incomplete. The paper copy of the sequence listing has been located and entered into the application file. The requirements of the communication mailed 6/19/01 are hereby withdrawn.

During the interview the examiner indicated that a restriction requirement would be made in the instant application and the restriction requirement is set forth below.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to a masked expression cassette.

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Group II, claim(s) 10-15, drawn to methods of controlling the expression of a protein of interest.

- 3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The methods of group II can be performed using other than the masked expression cassette of Group I.
- 4. During a telephone conversation with Eric Kron on 6/19/01 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-4. It was indicated by applicant representative that these claims would be pursued in a divisional application.
- 5. The application has been amended as follows:

Nonelected claims 5-15 have been canceled.

Claim 1 has been canceled and rewritten as new claim 16.

Claim 16. A masked expression cassette comprising a first strand comprising an RNA sequence which encodes a protein of interest wherein the RNA sequence is linked downstream of a flanking sequence, and a translation initiation site operably linked upstream of the RNA sequence: and, a second strand bound to the flanking sequence, wherein the second strand

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comprises an antisense sequence corresponding to the flanking sequence and a target nucleic acid sequence, where when the masked expression cassette is contacted with the target nucleic acid the second strand dissociates from the cassette allowing expression of the protein of interest.

In claim 2, line 1, "1" has been deleted and replaced with --16--.

In claim 3, line 1, "1" has been deleted and replaced with --16--.

In claim 3, line 1, "comprises" has been deleted and replaced with --is--.

In claim 4, line 1, "1" has been deleted and replaced with --16--.

6. The following is an examiner's statement of reasons for allowance: The composition claims related to the amended claims above were rejected under 35 U.S.C. 112, first paragraph. This rejection of the compositions was based on the utility asserted in the specification drawn to *in vivo* use. The specification however does include *in vitro* utilities (see page 3 and Figure 7, for example).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue



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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028.

SRM

June 20, 2001

SEAN MCGARRY PRIMARY EXAMINER

